

REMARKS

Claims 1-6, 8-14, and 21-30 are currently pending in this application. Claims 1, 8, 11, 21, 25, 28 and 30 have been amended. No claims have been canceled. No new matter has been added. Reconsideration of the claims and the remarks is respectfully requested.

Examiner Telephone Interview

On July 31, 2009, the Applicant's representatives, John Gatz and Bradley Taub, spoke with Examiner Turk to discuss the outstanding Office Action. Examiner Turk and the Applicant's representatives discussed the Section 102 rejections. Applicant is submitting a written response as suggested by the Examiner.

Ripley Declaration

To assist the Applicant in distinguishing the present invention over the applied references, the Applicant has attached a 37 C.F.R. § 1.132 Declaration from Mr. Paul M. Ripley.

Independent Claim 1

35 U.S.C. §§ 102/103 Rejections

Independent claim 1 recites, *inter alia*, (1) “an input reflector coupled with said input light guide for forming a portion of an optical communication path”; (2) “an output light guide coupled with said output reflector for forming a portion of said optical communication path”; (3) “a lancet in communication with said sample cavity . . . said lancet being adapted to collect and deposit test material within said sample cavity such that said test material is positioned to interact with said reagent”; and (4) “wherein at least one of said input light guide and said output light guide is formed by a wall structure to assist in guiding light along said optical communication path, said wall structure including a first end and a second end, said second end being coupled with said input reflector or said output reflector for forming a portion of said optical communication path.” (emphasis added). Meserol fails to disclose, teach, or suggest a format with such elements.

Meserol is directed to a cuvette 10 used in determining a concentration of glucose or other analyte of interest in a blood sample. Column 5, lines 8-21; ¶ 5 of Ripley Decl. Specifically, Meserol discloses a cuvette 10 having a closed wall 18. *See* FIGs. 2, 4-6; ¶ 5 of

Ripley Decl. The closed wall 18 is a molded sheet of material that forms the cavity 22 of the cuvette 10. ¶ 5 of Ripley Decl. The closed wall 18 is not a light guide having a wall structure with first and second ends as recited in claim 1. The closed wall 18 does not “assist in guiding light along [an] optical communication path” as recited in claim 1. (emphasis added). Rather, Meserol merely passes a beam of light 30 through the wall 18. *See, e.g.*, FIG. 5 of Meserol. Thus, Meserol fails to guide light with a wall structure as recited in claim 1. *See* ¶ 5 of Ripley Decl.

The Office Action states that “the optically transmissive portion of the cuvette wall 18 where light enters from source 32, and is enclosed within the walls” is an enclosed input light guide. Pages 2-3 of the Office Action. The Applicant respectfully disagrees. The wall 18 does not guide light as explained above. Moreover, the optically transmissive portion of the wall 18 is not coupled with an input reflector as recited in claim 1. Rather, as light from source 32 hits the wall 18, the light is refracted through and enters a second medium in the cavity 22. Meserol discloses that the second medium in the cavity 22 may be a medium such as optically transparent gel. Meserol, column 5, lines 8-20. After light refracts through the wall 18, the light travels through the optically transparent gel within the cuvette 10. Then, the light hits a second portion of the wall 18, and then the light hits a right angle 46. *See, e.g.*, Meserol, FIG. 5. Thus, the wall 18 does not guide light along an optical communication path from a light input, through an input light guide, and to an input reflector as recited in claim 1.

Meserol’s cuvette is designed with many medium transitions along the light path, which result in scattered light that is subsequently lost. ¶ 5 of Ripley Decl. Specifically, Meserol discloses eight medium transitions where light can be scattered and lost. *See, e.g.*, FIG. 5; ¶ 5 of Ripley Decl. When a sufficient amount of light is scattered and subsequently lost, it is difficult, if not impossible, to obtain an accurate analyte reading. ¶ 5 of Ripley Decl. Here, the Meserol device because of the lack of a well defined path that does not support directional wave guiding will give rise to considerable stray reflections resulting in less accurate analyte readings. *Id.*

In summary, Meserol does not disclose, teach, or suggest (1) a light guide for guiding light from a light input to an input reflector and an output light guide for guiding light from an output reflector to a light output and (2) direct connections between light guides and reflectors to minimize light loss due to scattering. ¶ 6 of Ripley Decl.

Thus, Meserol does not disclose, teach, or suggest the claimed optical communication path as recited in claim 1.

Additionally, Meserol fails to disclose, teach, or suggest “a lancet in communication with [a] sample cavity,” as recited in claim 1, which is acknowledged by the Office action as page 5. Meserol also fails to disclose, teach, or suggest a “lancet being adapted to collect and deposit test material within said sample cavity such that said test material is positioned to interact with [a] reagent,” as recited in claim 1. In an attempt to address one of the deficiencies of Meserol, the Office Action previously applied U.S. Patent No. 5,525,518 to Lundsgaard (“Lundsgaard”) to dependent claim 21. To expedite prosecution, the Applicant will comment on the same.

Lundsgaard is directed to a method of photometric in vitro determination of blood gas parameters. Lundsgaard, Abstract; ¶ 7 of Ripley Decl. Several examples of different blood gas parameters are given in the specification including a pH of the blood, carbon dioxide content, oxygen content and hemoglobin content, and oxygen saturation. Col. 8, lines 8-42 of Lundsgaard; ¶ 7 of Ripley Decl. Meserol, on the other hand, is directed to a cuvette used in determining a glucose concentration or other analyte of interest in a liquid blood sample. Column 5, lines 8-21 of Meserol; ¶ 7 of Ripley Decl.

Additionally, Lundsgaard discloses a needle 20 with a traditional plunger syringe that is typically used for large blood sampling in order to see the gases. *See* Lundsgaard, column 7, line 61 – column 8, line 2; ¶ 8 of Ripley Decl. However, the Meserol’s cuvette 10 is not of the type normally used for taking large quantities of blood. ¶ 8 of Ripley Decl. Rather, the opposite is true. ¶ 8 of Ripley Decl. Typically, only a small amount of blood sample is required to determine a glucose concentration or other analyte of interest. ¶ 8 of Ripley Decl.

Thus, one skilled in the art would not look to combine Meserol, which is directed to determining analyte concentrations in small blood samples, with Lundsgaard, which is directed to in vitro determination of blood gas parameters using larger blood sampling. ¶ 9 of Ripley Decl.

For at least these reasons, independent claim 1 and all claims depending thereon (claims 2-7 and 28) are not anticipated by and not rendered obvious over Meserol, Lundsgaard, or the combination thereof.

35 U.S.C. 103 Rejections

Independent claim 1 recites, *inter alia*, (1) “an input reflector coupled with said input light guide for forming a portion of an optical communication path”; (2) “an output light guide coupled with said output reflector for forming a portion of said optical communication path”; (3) “a lancet in communication with said sample cavity . . . said lancet being adapted to collect and deposit test material within said sample cavity such that said test material is positioned to interact with said reagent”; and (4) “wherein at least one of said input light guide and said output light guide is formed by a wall structure to assist in guiding light along said optical communication path, said wall structure including a first end and a second end, said second end being coupled with said input reflector or said output reflector for forming a portion of said optical communication path.” (emphasis added).

Lemelson fails to disclose, teach, or suggest a format with such elements. Moreover, the Office Action also acknowledges that Lemelson does not disclose wall structures with second ends being physically coupled to the input and output reflector. Page 6 of the Office Action.

Thus, for at least these reasons, independent claim 1 is not anticipated by or rendered obvious over Lemelson, Meserol, Lundsgaard, or any combination thereof.

Dependent claims 2-7 and 28

Dependent claims 2-7 and 28 all dependent from independent claim 1. Thus, for at least the same reasons discussed above in reference to independent claim 1, claims 2-7 and 28 are not anticipated by or rendered obvious over Meserol, Lemelson, Lundsgaard, or any combination thereof. For example, dependent claim 2 recites “a venting channel connected to said sample cavity, wherein said lancet is positioned within said venting channel.” Meserol, Lemelson, and Lundsgaard all fail to disclose, teach, or suggest a venting channel and a lancet positioned within a venting channel. Dependent claim 28 recites “said input light guide is formed by a first four-sided wall structure and said output light guide is formed by a second four-sided wall structure.” Meserol, Lemelson, and Lundsgaard all fail to disclose, teach, or suggest light guides with four-sided wall structures. Rather, Meserol discloses a wall 18 that is one sided and not a light guide, Lemelson discloses flexible light pipes 22, 24, 26, 28 that appear to be circular, and Lundsgaard fails to disclose any light guides.

Independent Claims 8 and 25

Independent claim 8 recites, *inter alia*, (1) “an input light guide being formed by a first wall structure having a first end and a second end, said second end being coupled with an input reflector”; (2) “an output light guide being formed by a second wall structure having a first end and a second end, said second end being coupled with an output reflector”; and (3) “a lancet in communication with said sample cavity, said lancet being adapted to collect and deposit test material within said sample cavity.” For at least the same reasons discussed above in reference to independent claim 1 with these similar elements, independent claim 8 and all claims depending therefrom (claims 9-14 and 21-24) are not anticipated by or rendered obvious over Meserol, Lemelson, Lundsgaard, or any combination thereof.

Independent claim 25 recites, *inter alia*, (1) “an input light guide coupled with an input reflector”; (2) “an output light guide coupled with an output reflector”; and (3) a lancet in communication with said sample cavity, said lancet being adapted to collect and deposit test material within said sample cavity.” For at least the same reasons discussed above in reference to independent claim 1 with these similar elements, independent claim 25 and all claims depending therefrom (claims 26-27 and 29-30) are not anticipated by or rendered obvious over Meserol, Lemelson, Lundsgaard, or any combination thereof.

CONCLUSION

The Applicant submits that the claims are in a condition for allowance and action toward that end is earnestly solicited. It is believed that no additional fees are due; however, should any fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from the Nixon Peabody Deposit Account No. 50-4181 (247082-000036USPT).

Respectfully submitted,

August 18, 2009

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